Towards customized intraocular lenses

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Chapter 3

Shape of the posterior cornea: a comparison of height data from three corneal topographers

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Abstract

PURPOSE: To compare three clinical corneal topographers in their ability to describe the posterior corneal shape.

METHODS: Thirty corneas of 30 healthy subjects were measured twice with a dual Scheimpflug camera (Galilei), a scanning slit system (Orbscan), and a single Scheimpflug camera (Pentacam). Elevation data describing the posterior corneal shape were fitted with Zernike polynomials. Mean values with standard deviation (SD), test-retest variability (coefficient of repeatability [CoR]), and inter-device variability were determined for the Zernike coefficients defocus, astigmatism (Z_2^{-2}, Z_2^{2}), and the higher-order terms coma, trefoil, and spherical aberration, for 5.5 and 8.0 mm diameter zones.

RESULTS: For the 5.5 mm diameter zone, CoRs ranged from 0.3 to 4.3 μm for Galilei, 1.6 to 5.2 μm for Orbscan, and 0.3 to 2.0 μm for Pentacam. Repeatability was similar for Galilei and Pentacam ($p = 0.43$) but significantly poorer for Orbscan ($p < 0.001$). Galilei and Pentacam CoRs were clearly smaller than the corresponding population SD for defocus, cardinal astigmatism (z[2,2]), coma, and spherical aberration. Orbscan failed to provide 8.0 mm diameter zone data. There was a significant bias (inter-device variability) between Galilei and Pentacam for the higher-order coefficients at both diameter zones (Orbscan omitted because of poor test-retest variability).

CONCLUSION: For the assessment of the posterior corneal shape, the repeatability is generally good for Galilei and Pentacam but poor for Orbscan. Inter-device variability between Galilei and Pentacam compromises the interchangeability of higher-order coefficients. For astigmatism, Galilei and Pentacam CoR and 95% limits of agreement correspond to typically 0.1 D per astigmatism term.

3.1 Introduction

Optical modeling of individual eyes is a clinically highly relevant topic due to forthcoming improvements of refractive surgical possibilities with new materials and technologies.[1] Optical modeling of individual eyes requires, among others, an accurate description of the shape of the cornea, which is the major refractive element of the eye. In an earlier study, we reported on the shape of the anterior surface of the human cornea, addressing its measurement with various topography systems and the fitting of elevation data by Zernike polynomials (chapter 2).[2] However, the anterior side of the cornea tells only one part of the story: the posterior side, even though the influence of the posterior corneal surface is relatively small due to the smaller difference in refractive index between the cornea and the aqueous humor,[3] contributes the optics of the eye as well.[4–7] For that reason it is important to know how accurately the posterior corneal shape can actually be measured.

In healthy corneas, the posterior corneal shape is related to the anterior corneal shape but not identical. As stated by Dubbelman et al., the posterior corneal surface compensates on average one-third of the anterior corneal astigmatism.[4] This was confirmed by Miyake et al. and they concluded that an individual assessment of the posterior corneal astigmatism is necessary for the power calculation of toric IOLs in eyes with high anterior corneal astigmatism.[7] In diseased corneas, irregularities in the posterior corneal shape may be larger, not limited to astigmatism, and no longer directly related to the anterior corneal shape. This explains the interest in the posterior corneal shape in DMEK and DSAEK patients.[8–11] Similarly, there will be a dissociation between the anterior and posterior corneal shape in patients who underwent corneal refractive surgery. This makes an accurate assessment of the posterior corneal shape pivotal for the future, when it comes to customized IOLs.

Several clinically available corneal topographers provide data concerning the posterior corneal shape: the Galilei, a dual Scheimpflug system, the Orbscan, a scanning slit system, and the Pentacam, a single Scheimpflug system. It is largely unknown to what extent data from these devices concerning the posterior corneal shape are interchangeable and reproducible; a comparison between these devices in this regard has – to the best of our knowledge - never been done.

The aim of this study was to determine (1) the intra- and (2) the inter-device variability of Zernike polynomial coefficients obtained by fitting posterior corneal elevation data with Zernike polynomials, in healthy subjects, using the abovementioned three clinical instruments. We also measured the corneas of the included subjects with the Dubbelman Scheimpflug system.[4] Although the Dubbelman system cannot be considered a gold standard because it assumes a conic shape of the corneal surfaces, this measurement provides an independent verification of the overall procedure (exporting data from commercial devices, fitting the data by Zernike polynomials, and reconstructing the shape from the resulting coefficients) and may be helpful for interpreting the data from the clinical devices in case of systematic bias between the instruments.

3.2 Methods

3.2.1 Subjects

The subjects were the same as those in our previous study (chapter 2).[2] They were recruited by advertising and were 18 years of age or older. The sample size of 30 subjects allowed us to detect differences in aberrations of approximately 0.75 SD of the distribution in the population. The exclusion criteria applied were any history of corneal eye disease, refractive surgery, and contact lens wear within 2 years prior to the measurements. Table 3.1 shows the general characteristics of the included subjects. The ethics board of the University Medical Center Groningen (UMCG) approved the study protocol. All participants provided written informed consent. The study followed the tenets of the Declaration of Helsinki.

3.2.2 Measurement procedure

For both eyes of each subject, two valid measurements, as indicated by each instrument, were performed with the Galilei (Galilei G2, software version 5.2; Ziemer Ophthalmic Systems AG, Port, Switzerland), the Orbscan (Orbscan IIz, software version 3.12.57sp3, Bausch & Lomb, Bridgewater, NJ, USA), and the Pentacam (Pentacam High Resolution, software v6.03b08; Oculus Optikgeräte GmbH, Wetzlar, Germany). The subject's head stayed within the head rest during these measurements. After these measurements,

Parameter	**Median**	**Range (min, max)**
Age (y)	24	19, 59
Refraction (D)		
Right eye		
Spherical Equivalent	-1.50	-13.00, +0.50
Astigmatism	-0.50	-4.00, 0.00
Left eye		
Spherical Equivalent	-1.25	-13.75, 0.00
Astigmatism	-0.50	-2.00, -0.25
Axial length (mm)		
Right eye	23.64	22.16, 28.74
Left eye	23.62	21.97, 29.18
Keratometry (mm)		
Right eye		
K1	7.87	7.30, 8.26
K2	7.72	7.25, 8.06
Left eye		
K1	7.86	7.34, 8.30
K2	7.72	7.28, 8.10

K1 = flattest radius of curvature;
K2 = steepest radius of curvature

Table 3.1: General characteristics of the population

the subject was asked to sit backwards and the instrument was brought to a neutral position. Then another two valid measurements for a randomly chosen eye were performed. Furthermore, the eyes were measured with a prototype Scheimpflug system that was described and validated by Dubbelman et al.[4] To characterize the subject's eyes, autorefraction and autokeratometry (ARK, Topcon Corp., Tokyo, Japan) and axial length measurements (IOLMaster, Carl Zeiss Meditec AG, Jena, Germany) were also performed. The pupils were not dilated during the measurements.

3.2.3 Corneal topographers

The three corneal topographers used in this study are all based on different measurement principles. The Orbscan combines a scanning-slit with 20 Placido disk rings, where the scanning-slit provides the information of the posterior corneal elevation. Both the Galilei and Pentacam use a rotating Scheimpflug camera technique to assess the corneal shape. However, the Galilei uses the average image of two oppositely placed cameras, claiming this improves the accuracy of the measurement,[12] while the Pentacam only uses one rotating Scheimpflug camera. Although the measurement principles of all three topographers are known, the algorithms used to eventually produce elevation data is unknown and the instruments thus practically function as black boxes. A detailed description of the instruments can be found in our previous study (chapter 2).[2]

3.2.4 Data analysis

Although both eyes were measured for each subject, it is well-known that the aberrations of fellow eyes are not independent of each other.[13,14] Since the shape of the cornea is directly related to its aberrations,[15] we included only one eye per subject in the statistical analysis (for the interdevice variability the right eye; for the test-retest analysis the eye that was retested).

Elevation data were exported from the three devices. The Orbscan and Galilei provide elevation data in polar coordinates; the Pentacam provides elevation data in a Cartesian grid; these data were transformed into polar coordinates. The exported data were centered with respect to the posterior apex of the cornea. The posterior apex was obtained by centroiding the positions of the data points that shared the minimum elevation value of the posterior corneal surface. Subsequently, the elevation data were fitted with Zernike polynomials by solving a set of linear equations using a least-squares method. The fitting procedure was programmed in Matlab (version 7.10.0 R2010a; Mathworks, Natick, MA, USA) (chapter 2).[2] The fitting procedure was performed up to the 8th Zernike order (45 terms) and for two different optical zones: 5.5 and 8 mm diameter. For reporting the Zernike polynomials, we adhered to the ISO standards used for reporting ophthalmic aberrations.[16]

Eight terms of the Zernike polynomials were used for the analysis: the defocus term (Z_2^0), both astigmatism terms (Z_2^{-2} and Z_2^2), both coma terms (Z_3^{-1} and Z_3^1), both trefoil terms (Z_3^{-3} and Z_3^3), and the spherical aberration term (Z_4^0).For each subject, the coefficients of the Zernike polynomials were averaged over the repeat measurements performed without repositioning the head; test-retest variability was analyzed by comparing the average of the coefficients obtained before the repositioning with the average of the coefficients obtained after the repositioning.

For the test-retest variability, the coefficient of repeatability was calculated, as twice the standard deviation of the differences between the first (test) and second (retest) measurement.[17] We used a General Linear Model to determine whether the test-retest variability was related to the Zernike coefficient and the corneal topographer. Here, the dependent variable was the unsigned difference between test and retest and the independent variables were the type of topographer and the Zernike polynomial coefficient. Since the Orbscan did not provide posterior elevation data over the 8.0 mm diameter zone, the analysis was performed for 5.5 mm (with the Orbscan) and 8.0 mm diameter zone (without the Orbscan) separately.

For the comparison of the Zernike polynomial coefficients between the devices, Bland-Altman analysis was used.[18,19] Results for the interdevice variability were presented as the mean difference (bias) with corresponding 95% limits of agreement, being the mean difference $\pm$ twice the standard deviation of the differences.

The Dubbelman Scheimpflug system does not yield raw height data but a Scheimpflug image of the eye in the meridian that was measured. As this system has to be rotated manually and each measurement takes several minutes, images were made at two meridians only: 0 degree (horizontal meridian) and 90 degrees (vertical meridian). From the Scheimpflug images, a description of the shape of the cornea at the measured meridian was obtained by fitting the photographs using Equation 3.1:

$$y = \frac{c(x - x_0)^2}{1 + \sqrt{1 - kc^2(x - x_0)^2}} \tag{3.1}$$

This equation describes an aspheric surface where $c = 1/r$ is the curvature at the apex of the cornea (x_0, y_0). The parameter k indicates the degree to which an aspheric surface differs from the equivalent spherical form. According to the value of k, the surface is hyperboloid when $k < 0$, a paraboloid when $k = 0$, a prolate ellipsoid when $0 < k < 1$, a circle when $k = 1$, and an oblate spheroid when $k > 1$. Three other parameters that are commonly used to describe a conic are the Q value (where $k = Q + 1$), the shape factor p (where $k = p$), and the eccentricity e (where $k = e^2 + 1$).[3,4,20]

For the comparison of the clinical devices with the Dubbelman Scheimpflug system, the shape of the cornea at the horizontal meridian was calculated from the 3D-Zernike fit and compared to the corresponding shape as retrieved from the Dubbelman Scheimpflug images using Equation 3.1. The differences between the shapes were subsequently plotted to enable a comparison. This comparison was made at a diameter of 6.5 mm as this was the maximum diameter available for all subjects in the Dubbelman Scheimpflug data (the 3D-Zernike fits of the clinical devices were also performed at 6.5 mm diameter for this comparison).

All statistical analyses were performed using SPSS (version 20.0; IBM corp., Armonk, NY, USA). A p-value of 0.05 or less was considered statistically significant; Bonferroni correction was applied when appropriate.

3.3 Results

Table 3.2 shows the results of the test-retest analysis for the 5.5 (A) and 8.0 (B) diameter zones. The characteristics of the study population (mean and standard deviation) were added as a reference. The Orbscan provided posterior elevation data up to a diameter zone of approximately 6 mm only, resulting in missing data for the 8 mm diameter zone. For the Orbscan (Table 3.2A), the test-retest variability was of the same order of magnitude as the variability in the population. For the Galilei and Pentacam (Tables 3.2A and 3.2B), the test-retest variability was generally smaller than the corresponding variability in the study population, except for oblique astigmatism (Z_2^{-2}) and both trefoil terms (note that the coefficient of repeatability is twice the standard deviation of the differences whereas the variability in the study population is presented as a single standard deviation). In the General Linear Model applied to the 5.5 mm diameter zone data, both the Zernike coefficient ($p < 0.001$) and the corneal topographer ($p < 0.001$) had a significant influence on the repeatability. In the post-hoc Bonferroni analysis, the Orbscan deviated significantly from the Galilei and Pentacam ($p < 0.001$), whereas the Galilei and Pentacam showed no statistically significant difference ($p < 0.43$). For the 8.0 mm diameter zone, there was no significant difference ($p < 0.79$) between the Galilei and Pentacam either.

Table 3.3 presents the results for the paired comparisons of the Galilei and the Pentacam, for both 5.5 and 8.0 mm diameter zone (the Orbscan was omitted here because of its large test-retest variability and lack of data for the 8 mm diameter zone). Data are

	A. 5.5 mm diameter					
	Galilei		Orbscan		Pentacam	
Zernike coefficient	**Population mean (SD; μm)**	**CoR (μm)**	**Population mean (SD; μm)**	**CoR (μm)**	**Population mean (SD; μm)**	**CoR (μm)**
Astigmatism (Z_2^{-2})	+0.12 (1.29)	1.37	+1.29 (2.10)	2.71	-0.44 (1.71)	1.91
Defocus (Z_2^0)	+176 (7.2)	4.32	+188 (6.19)	4.40	+178 (7.0)	1.20
Astigmatism (Z_2^2)	-6.59 (2.32)	1.15	-8.13 (3.87)	5.21	-6.31 (2.60)	1.99
Trefoil (Z_3^{-3})	-0.38 (0.53)	0.90	-0.76 (0.90)	3.91	-0.10 (0.43)	0.73
Coma (Z_3^{-1})	+0.24 (0.81)	0.79	+0.83 (1.32)	3.41	+0.64 (0.82)	0.36
Coma (Z_3^1)	-0.11 (0.77)	0.67	-1.08 (1.21)	3.36	-0.20 (0.52)	0.27
Trefoil (Z_3^3)	+0.83 (0.56)	0.98	+0.52 (1.12)	3.01	-0.07 (0.31)	0.72
Spherical aberration (Z_4^0)	+1.61 (0.58)	0.25	+0.30 (0.83)	1.56	+2.39 (0.45)	0.25

8.0 mm diameter						
	Galilei		Pentacam		Orbscan	
Zernike coefficient	**Population mean (SD; μm)**	**CoR (μm)**	**Population mean (SD; μm)**	**CoR (μm)**	**Population mean (SD; μm)**	**CoR (μm)**
Astigmatism (Z_2^{-2})	-1.68 (2.61)	3.69	-2.22 (3.90)	4.33	N/A	N/A
Defocus (Z_2^0)	+388 (18.0)	1.53	+395 (18.6)	2.23	N/A	N/A
Astigmatism (Z_2^2)	-12.7 (5.11)	1.47	-13.4 (5.91)	3.99	N/A	N/A
Trefoil (Z_3^{-3})	-1.00 (1.44)	1.85	-0.13 (0.72)	1.52	N/A	N/A
Coma (Z_3^{-1})	-1.13 (2.29)	1.72	-0.65 (2.38)	0.96	N/A	N/A
Coma (Z_3^1)	-2.18 (2.49)	2.20	-1.73 (2.40)	0.74	N/A	N/A
Trefoil (Z_3^3)	+1.56 (1.22)	2.41	+0.32 (0.59)	1.17	N/A	N/A
Spherical aberration (Z_4^0)	+7.35 (2.53)	1.47	+8.28 (2.63)	0.54	N/A	N/A

Table 3.2: Test-retest variability of Galilei, Orbscan, and Pentacam measurements over the 5.5 mm (A) and 8.0 mm (B) diameter zone of the posterior corneal surface presented as the coefficient of repeatability with the characteristics of the population as reference.

given as mean difference (bias) with the 95% limits of agreement between brackets, for all Zernike polynomial coefficients addressed in this study. The bias was significantly different from 0 at a Bonferroni-corrected p-value of 0.003 $(0.05/16)$ for all coefficients except for both astigmatism terms (z2(-)2) over both diameter zones and one trefoil term (z3-3) over the 5.5 mm diameter zone. Figures 3.1 and 3.2 show the corresponding scatter (A-C) and Bland-Altman (D-F) plots for the lower-order (defocus, and astigmatism; Figure 3.1) and higher-order (coma and spherical aberration; Figure 3.2) coefficients at 5.5 mm diameter zone, respectively (trefoil was omitted here because of its large test-retest variability). Generally, the associations between Galilei and Pentacam are stronger for the lower-order coefficients (Fig. 3.1A-C) than for the higher-order coefficients (Fig. 3.2A-C) and, especially for the higher-order coefficients, a clear bias between the Galilei and Pentacam exists (systematic deviation from the line y=x).

Figure 3.3 gives a comparison between the shape of the posterior cornea as reconstructed from the fits to the height data from the Galilei and Pentacam and the shape as assessed with the Dubbelman Scheimpflug system, for the horizontal meridian. Data are presented as mean shape over the population (A) and as the corresponding difference between the Dubbelman and the two clinical devices (B). A similar pattern was

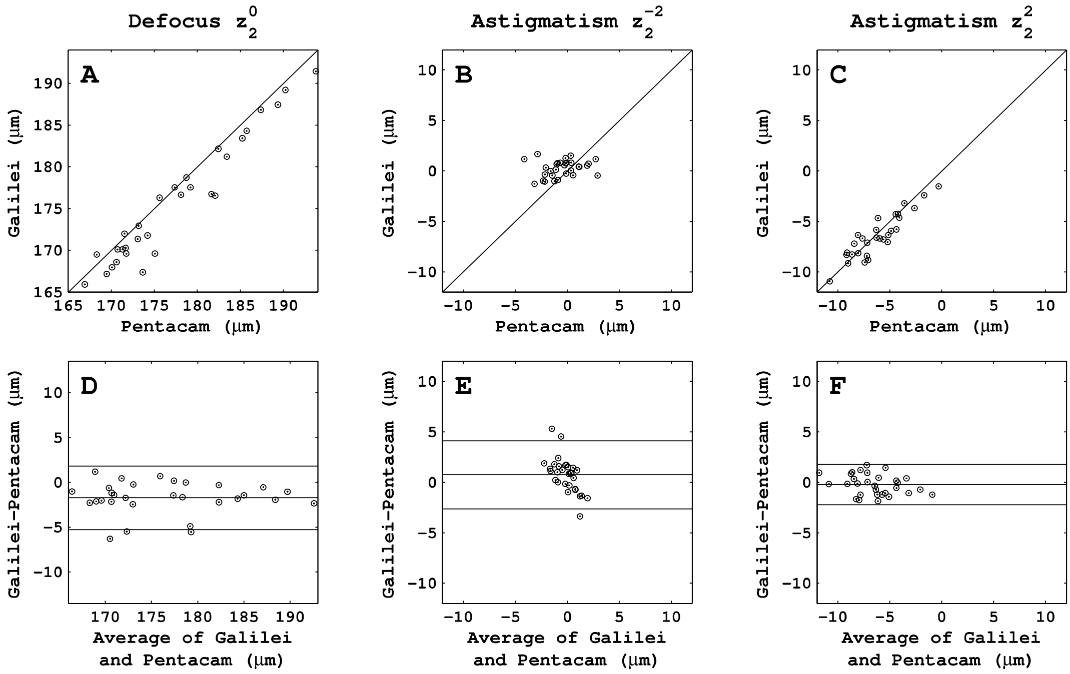

Figure 3.1: Interdevice variability scatter plots (A to C) showing the Zernike polynomial coefficients for the lower-order terms at 5.5 mm diameter zone derived by the Galilei and Pentacam, with corresponding Bland-Altman plots (D to F). Horizontal lines denote mean difference (bias) and 95% Limits of agreement.).

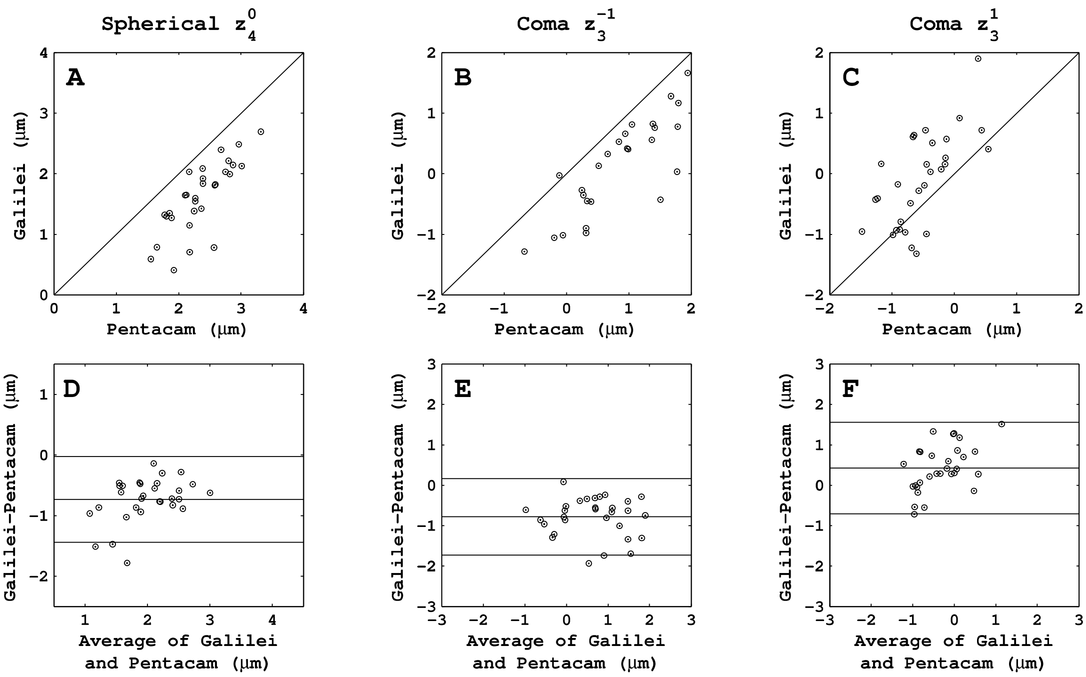

Figure 3.2: Interdevice variability scatter plots (A to C) showing the Zernike polynomial coefficients for the higher-order terms at 5.5 mm diameter zone derived by the Galilei and Pentacam, with corresponding Bland-Altman plots (D to F). Horizontal lines denote mean difference (bias) and 95% Limits of agreement.

	Paired difference Galilei-Pentacam	
	5.5 mm diameter	**8.0 mm diameter**
Astigmatism (Z_2^{-2})	+0.63 (-1.74; +2.99)	+0.70 (-3.60; +5.00)
Defocus (Z_2^{0})	-1.73 (-5.36; +1.89)*	-5.82 (-10.6; -0.99)*
Astigmatism (Z_2^{2})	-0.24 (-2.27; +1.79)	+0.49 (-4.19; +5.17)
Trefoil (Z_3^{-3})	-0.20 (-1.75; +1.34)	-0.91 (-3.57; +1.76)*
Coma (Z_3^{-1})	-0.78 (-1.75; +0.18)*	-1.51 (-3.29; +0.27)*
Coma (Z_3^{1})	+0.43 (-0.73; +1.58)*	+0.38 (-2.29; +3.05)
Trefoil (Z_3^{3})	+0.95 (-0.46; +2.37)*	+1.19 (-1.05; +3.43)*
Spherical aberration (Z_4^{0})	-0.73 (-1.46; -0.01)*	-0.84 (-2.36; +0.70)*

* = significantly different at a Bonferroni-corrected p-value of 0.003

Table 3.3: Interdevice variability for Galilei versus Pentacam presented as mean difference with 95% limits of agreement between brackets for 5.5 and 8.0 mm diameter zone.

observed for both clinical devices: corneal flattening towards the periphery was more pronounced with the clinical devices than with the Dubbelman Scheimpflug system.

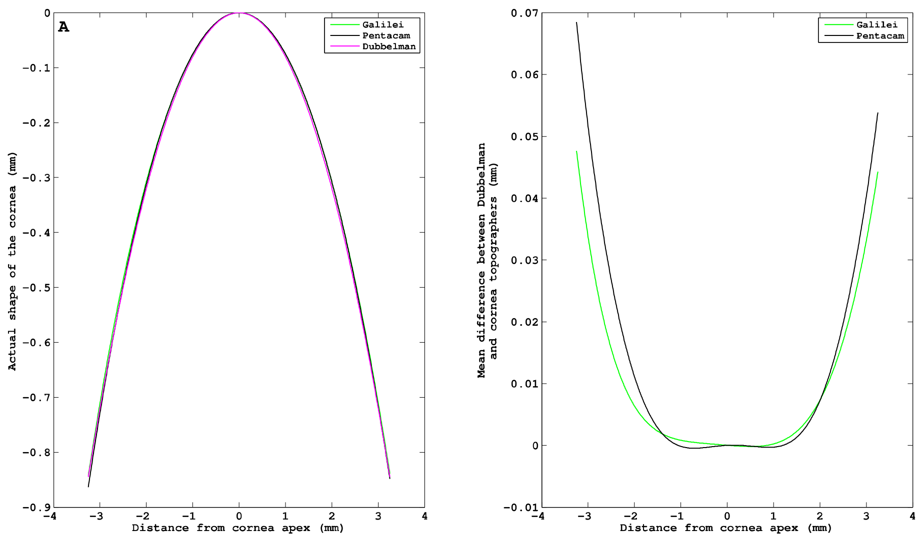

Figure 3.3: Height of the posterior cornea (mm) over the horizontal meridian as assessed with the Dubbelman Scheimpflug system and the Galilei and Pentacam, presented as the population mean (A) with corresponding difference between the Dubbelman and the two clinical devices (B).

3.4 Discussion

Of the three devices evaluated concerning their ability to assess the posterior corneal shape, the Orbscan showed by far the largest test-retest variability, hampering its use for this purpose. The Galilei and Pentacam had a similar test-retest variability and this variability was clearly smaller than the variability in the population, except for oblique astigmatism (Z_2^{-2}) and both trefoil terms. For most Zernike coefficients, Galilei and Pentacam showed a significant bias, most pronounced for the higher-order Zernike coefficients. With the lack of a gold standard, however, it is not possible to determine which instrument is most accurate.

In an earlier study, we found for the Galilei and Pentacam that the coefficients of repeatability of the Zernike coefficients describing the anterior corneal shape were small compared to the variability in the study population, with the Pentacam being superior (chapter 2).[2] In the current study, we found that the coefficients of repeatability of the Zernike coefficients describing the posterior corneal shape were relatively large compared to their anterior counterparts, but, for most coefficients, still small compared to the variability in the population (Table 3.2). For the posterior corneal shape, the repeatability of the Galilei and Pentacam were equal, and therefore it is not possible to prefer one over the other. The Orbscan showed a poor repeatability, both for the posterior (this study) and the anterior corneal surface (chapter 2).[2]

A comparison of the Galilei and Pentacam showed that the individual Zernike coefficients assessed by both instruments were not interchangeable. Most coefficients differed statistically significantly; the only non-significant biases were found for both astigmatism terms over both diameter zones and one trefoil term over the 5.5 mm diameter zone. However, more importantly, the mean paired difference between the Galilei and Pentacam (Table 3.3) are at least of the order of magnitude of the coefficients of repeatability of the corneal topographers (Table 3.2A and 3.2B). This indicates that the bias is not only statistically significant, but also clinically relevant, since the bias is non-negligible compared to the variability between measurements. Figure 2 further verifies the clinically relevant bias of the higher-order Zernike coefficients. Using the average astigmatic contribution of the posterior corneal surface of approximately 0.33 D from the literature,[4,7,21] we can estimate that 1 μm corresponds to approximately 0.05 D for the 5.5 mm diameter zone. Hence, the coefficients of repeatability of Galilei and Pentacam and the 95% limits of agreement between these devices are typically 0.1 D per astigmatism term. A potentially significant axis error may also exist.

A structural offset can be caused by either the instrument methodology or the instrument processing. Although both instruments are essentially black boxes, we do know that they differ in their measurement method. The Galilei uses two Scheimpflug cameras combined with a Placido disc system, while the Pentacam assesses the shape of the cornea with one Scheimpflug camera. By taking the average over the two Scheimpflug cameras it is argued by the manufacturer of the Galilei that the corneal thickness could be calculated more precisely by compensating unintentional misalignment,[12] especially in the peripheral areas. We showed, however, that the bias between the Pentacam and Galilei compared to the Dubbelman Scheimpflug was essentially similar (Fig. 3.3), which contradicts a structural better performance of the Galilei. Nevertheless, the different measurements techniques could still explain the bias between the instruments, but due to lack of a gold standard, it is not possible to state that one corneal topographer is more accurate than the other. For the clinician it is important to realize that the measurements of the posterior corneal shape by the Galilei and Pentacam are not without more interchangeable.

The shape of the posterior corneal surface imparts a modicum of influence on the aberrations of a healthy human eye, due to the small difference between the refractive index of the cornea and the aqueous humor.[3] However, it should not be ignored, and its importance is demonstrated by the fact that, although the posterior side constitutes only about 10% of the power of the cornea, it compensates for approximately one-third of the astigmatism induced by the anterior cornea.[4,7,21] Recent studies have also shown that posterior corneal astigmatism has an impact on correcting corneal astigmatism with toric intraocular lenses.[21,22] Furthermore, Sicam et al. stated that a one-surface model of the cornea is not sufficient when predicting the spherical aberration of the cornea.[5] The shape of the posterior corneal surface is therefore expected to remain a topic of interest for upcoming clinical research.

In conclusion, the Galilei and the Pentacam have a very similar and good repeatability in the measurement of the posterior corneal shape, except for oblique astigmatism and both trefoil terms. The Orbscan has a poor repeatability and therefore the obtained measurements of the posterior corneal shape should be regarded as inaccurate. Thus, from the studied devices, the Galilei and Pentacam should be preferred over the Orbscan when the posterior corneal shape is the topic of interest. Their test results essentially agree for the lower-order Zernike coefficients but differ systematically for the higher-order coefficients.

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